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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/178,126 10/23/98 STIVLAND

T 1001.1294101

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QM32/0302

EXAMINER

CHENEY, K

ART UNIT

PAPER NUMBER

3762

7

DATE MAILED:

03/02/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/178,126

Applicant(s)
Stivland et al

Examiner
Kelly M. Cheney

Group Art Unit
3762



☒ Responsive to communication(s) filed on Oct 23, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 73 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-48 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-48 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on Oct 23, 1998 is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4, 6

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3762

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: 537 in Figure 8.

Correction is required.

Specification

2. The disclosure is objected to because of the following informalities: Page 17, line 1: Outer tube 712 should be outer tube 702.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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4. Claims 1-6, 10, 13-15, 27-32, 35, 38-41, 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Miraki (5389087). Miraki discloses a catheter comprising, a first tube (22) having a lumen (40), an inside and outside wall surface, an orifice (62) and being formed of a flexible material, a second tube (74) having a lumen (78), an inside and outside surface, inserted through and extending distally from the orifice (Fig. 18) and being formed of a lubricious material such as high density polyethylene, a bonding region including bonding between the first tube outside surface and the second tube outside surface proximal of the orifice and between the first tube inside surface and the second tube outside surface distal of the orifice.

5. Claims 1-7, 10, 13-16, 27-33, 35, 38-41, 47-48 are rejected under 35 U.S.C. 102(e) as being anticipated by Sirhan et al (5743875). Sirhan discloses a catheter comprising, a first tube (30) having a lumen (50), an inside and outside wall surface, an orifice (42) and being formed of a flexible material, a second tube (33) having a lumen (40), an inside and outside surface, inserted through and extending distally from the orifice (Fig. 6) and being formed of a lubricious material such as high density polyethylene, a bonding region including bonding between the first tube outside surface and the second tube outside surface proximal of the orifice and between the first tube inside surface and the second tube outside surface distal of the orifice. The first and second tubes include inner and outer layers that can be the same or different materials including polyethylene and polyamide (9:46-58), the tubes can be composed of materials that are the same or different proximal and distal the orifice, and it is well known in the art to form tubes of several

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layers when different properties are desired for a single tube such as an inner lubricious layer to reduce friction and an outer layer of a polyamide to provide flexibility.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-9, 11-12, 17-26, 34-37, 42-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sirhan et al as applied to the claims above and in view of Gold et al (4636346). Sirhan discloses all the features of the applicant's invention as stated in the rejection above except for the tie-layer disposed between the inside and outside layers. Gold et al disclose a catheter comprising an inner lubricious layer, an outer flexible layer and an intermediate layer or tie-layer disposed between the inner and outer layers. It would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use a tie-layer as taught by Gold to bond two chemically dissimilar materials when it is desired to have an inner lubricious layer and a flexible outer layer.

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Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Maillard et al (3561493), Fontirroche et al (5820594), Flynn (5085649), Woo et al (5356709), Macaulay et al (5234416), Fanselow et al (5562127), Jang et al (4898591), Hobbs et al (5584821), Schreiner (5904670), and Fugoso et al (5964778) disclose tubes composed of multiple layers of materials including tie-layers between inner and outer layers. Euteneuer et al (4943278), Keith (5156594), Blaeser et al (5490837), and Lafontaine et al (565468) disclose devices analogous to the applicant's invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kelly M. Cheney whose telephone number is (703) 306-5444.

kmc

kmc

February 24, 2000

Mark O. Polutta
MARK O. POLUTTA
PRIMARY EXAMINER